DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2014

DenMat Holdings, LLC
C/O Ms. Helen Ragus
Regulatory Specialist
1017 W. Central Avenue
Lompoc, California, 93436

Re: K140537
Trade/Device Name: tenure®4G
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: II
Product Code: KLE
Dated: May 27, 2014
Received: May 27, 2014

Dear Ms. Ragus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140537

Device Name
tenure®4G

Indications for Use *(Describe)*

tenure®4G is recommended for the following types of applications:
1) All routine direct and indirect resin composite bonding
2) Porcelain, ceramic veneers, amalgams, precious and semi-precious metals bonding
3) Indirect gold, porcelain and ceramic inlays and onlays bonding
4) Desensitization of root or dentin prior to impressions or temporaries
5) Preparation desensitization of crown prior to impressions or temporaries

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DenMat

1017 West Central Avenue
Lompoc, CA 93436
805-346-3700
www.denmat.com

K140537

V. 510(k) SUMMARY

Submitter:

Owner's Name:	DenMat Holdings, LLC
Address:	1017 W. Central Avenue Lompoc, CA 93436 U.S.A.
Phone Number:	805 346 3700
Fax Number:	805 347 7940
Contact Person:	Helen Ragus Regulatory Specialist 805 346 3700, X2932 hragus@denmat.com
Date of Summary Preparation:	February 24, 2014

Device Name:

Trade Name:	tenure® 4G
Common Name:	Bonding Agent
Classification Name:	Agent, Tooth Bonding

Predicate Devices:

ALL-BOND 2 by Bisco	K910860
Tenure MPB (Den-Mat Tenure)	K872510

Description of the Device

tenure®*4G* is DenMat's next generation of its popular Tenure MPB System with greater bond strength and sensitivity control. It is a 4th generation multi-purpose, self-cure adhesive system for bonding any resin restorative to all intraoral surfaces. They are polymerizable dental monomer resins that are chemically-cured with the reaction initiated when the two parts are mixed together. These polymers form strong leak and stain resistant bonds between the dental surface and restorations placed over them.

Intended Use of the Device

tenure®*4G* is intended to be used as a resin tooth bonding agent. It is used for composite bonding of porcelain and metals, as well as for desensitizing root, dentin or crown prior to impressions or temporaries.

Indications of Use of the Device

tenure®*4G* is recommended for the following types of applications:

1) All routine direct and indirect resin composite bonding.
2) Porcelain, ceramic veneers, amalgams, precious and semi-precious metals bonding.
3) Indirect gold, porcelain and ceramic inlays and onlays bonding.
4) Desensitization of root or dentin prior to impressions and temporaries.
5) Preparation desensitization of crown prior to impression or temporaries.

Substantial Equivalence Discussion

1) Intended Uses/Indications for Use

tenure®*4G* and the predicate devices are intended to be used as resin tooth bonding agents. They are used for composite bonding of porcelain and metals, as well as for desensitizing root, dentin or crown prior to impressions or temporaries.

tenure®*4G* and Tenure MPB are recommended for the following types of applications: all routine direct and indirect resin composite bonding; porcelain, ceramic veneers, amalgams, precious and semi-precious metals bonding; indirect gold, porcelain and ceramic inlays and onlays bonding; desensitization of root or dentin prior to impressions and temporaries; and preparation desensitization of crown prior to impression or temporaries.

ALL-BOND 2 applications include bonding to dentin, enamel, new or old composite, precious and non-precious casting alloys, silane treated porcelain, and new or old amalgam; and treatment of tooth sensitivity.

Scientific literature have been evaluated to determine safety and efficacy of similar products used for the same indications. The intended uses and indications for use of the subject device are substantially equivalent to those of the predicate devices.

2) Chemical Components/Safety

Chemical components in tenure®*4G* have been used in the predicate devices. Scientific literature have been evaluated to determine safety and efficacy of similar products used for the same indications. The predicate devices have not been a focus of any advisory notice or recalls according to the post-market adverse event reporting requirements in the United States. The conclusion can be made that the safety of the subject device is substantially equivalent to those of the predicate devices.

3) Technological Characteristics/Effectiveness and Performance

There are no international standards concerning performance for these types of devices. Scientific literature have been evaluated to determine safety and efficacy of similar products used for the same indications. The physical/mechanical properties of tenure®*4G* were tested in the lab using R&D test protocols. Results of shear bond testing indicate that tenure®*4G* was as effective and performs as good as or even better than the predicate devices. The conclusion can be made that the effectiveness and performance of the subject device is substantially equivalent to those of the predicate devices.

Biocompatibility

The subject device is categorized as an external communicating device with contact to tissue/bone/dentin and is a permanent contact device. tenure®*4G*'s chemical ingredients are equivalent to those of the predicate devices. All devices are made of materials with a long history of safe use. The predicate devices have not been a focus of any advisory notice or recalls according to the post-market adverse event reporting requirements in the United States. Accordingly, conclusion can be made that the subject device is substantially equivalent in safety to the predicate devices.

Comparative Performance Data

tenure®*4G*

	Porcelain			**Enamel**			**Dentin**	
	psi	MPa		psi	MPa		psi	MPa
Mean	1907.14	13.149	Mean	1851.84	12.768	Mean	3776.07	26.035
Stdev	294.42	2.030	Stdev	512.14	3.531	Stdev	478.64	3.300

ALL-BOND 2

	Porcelain			Enamel			Dentin	
	psi	MPa		psi	MPa		psi	MPa
Mean	1627.21	11.219	Mean	1147.21	7.910	Mean	2830.62	19.516
Stdev	656.00	4.523	Stdev	549.74	3.790	Stdev	217.68	1.501

Tenure MPB

	Porcelain			Enamel			Dentin	
	psi	MPa		psi	MPa		Psi	MPa
Mean	2041.29	14.074	Mean	1485.50	10.242	Mean	3027.60	20.875
Stdev	177.37	1.223	Stdev	659.45	4.547	Stdev	410.47	2.830

Summary of Features and Characteristics of the Device Compared to the Predicate Device:

Product	510(k)	Applications	Chemical Compositon	Technique Application
tenure®*4G*		- All routine direct and indirect resin composite bonding - Porcelain, ceramic veneers, amalgams, precious and semi-precious metals bonding - Indirect gold, porcelain and ceramic inlays and onlays bonding - Desensitization of root or dentin prior to impressions and temporaries - Preparation desensitization of crown prior to impression or temporaries	- Self-cure - Methacrylate resin based - Contains acetone solvent - Contains ethanol solvent	Total-Etch
ALL-BOND 2	K910860	- All dental surfaces including precious and non precious casting alloys, and amalgam bonding - Root sensitivity treatment	- Self-Cure - Methacrylate resin based - Contains acetone solvent - Contains ethanol solvent	Total-Etch

Tenure Multi-purpose Bonding	K872510	- All routine direct and indirect resin composite bonding - Porcelain, ceramic veneers, amalgams, precious and semi-precious metals bonding - Indirect gold, porcelain and ceramic inlays and onlays bonding - Desensitization of root or dentin prior to impressions and temporaries - Preparation desensitization of crown prior to impression or temporaries	- Self-Cure - Methacrylate resin based - Contains acetone solvent	Total -Etch

Conclusion

The information provided in this 510(k) submission demonstrates that tenure® *4G* is substantially equivalent to the predicate devices All-Bond 2 and Tenure MPB in terms of intended use, indications for use, chemical composition and physical properties.

It is concluded that the information supplied in this submission has proven the safety and efficacy of this product.

1-CD

K140537/S2

FDA CDRH DMC

MAY 27 2014

Received

510(k) COVER LETTER

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: K140537/S001

Type of Submission:	Traditional
Trade Name:	tenure®*4G*
Common Name:	Dental Bonding Agent
Classification Regulation:	872.3200
Device Class:	II
Panel:	Dental
Product Code:	KLE
510(k) Submitter:	DenMat Holdings, LLC
Establishment Registration #:	2018957
Contact Person:	Helen Ragus Regulatory Specialist
Phone Number:	805 346-3700, X2932

Dear Sir or Madam,

In Reference to 510(k) number K140537/S001, please find the attached response addressing the elements identified as missing or inconsistent in the provided checklist attached to Acceptance Review Notification - Refuse To Accept (RTA) dated May 21, 2014.

In addition, 2 pages from the response to the FDA Acceptance Review Notification – Refuse to Accept dated March 18, 2014 and received by the FDA on 5/8/14 (eCopy 5/13/14) are also provided with corrected information.

1) In Response to Section C. Substantial Equivalence Discussion, the 510(k) predicate device number for Tenure MPB (K801216) was listed in error instead of the correct 510(k) K872510.
2) In Response to Section G. Biocompatibility, water was listed with the incorrect chemical name. The corrected information simply listed it as water.

Corrections were also made to the initial submission application received by the FDA on 3/4/14 where the incorrect predicate device for Tenure MPB (K801216) was listed instead of the correct 510(k) K872510.

1) I. 510(k) Cover Letter (page 2)

2) V. 510(k) Summary (Summary of Features and Characteristics of the Device Compared to the Predicate Device) (page 16)
3) X. Executive Summary (Features and Characteristics of the Device Compared to the Predicate Device) (page 23)
4) XII. Substantial Equivalence Discussion (Comparison of Features and Characteristics) (page 30)

In accordance to Section 745A (b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), an eCopy in the form of a CD is submitted with the paper copy,

If you have any questions and/or concerns, please call or e-mail me using the information below.

Sincerely,

Helen Ragus

Helen Ragus
Regulatory Specialist
(805) 346-3700, X2932
hragus@denmat.com

1-CD

K140537/S001

510(k) COVER LETTER

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 13 2014
Received

Reference: K140537/S001

Type of Submission:	Traditional
Trade Name:	tenure®4G
Common Name:	Dental Bonding Agent
Classification Regulation:	872.3200
Device Class:	II
Panel:	Dental
Product Code:	KLE
510(k) Submitter:	DenMat Holdings, LLC
Establishment Registration #:	2018957
Contact Person:	Helen Ragus Regulatory Specialist
Phone Number:	805 346-3700, X2932

Dear Sir or Madam,

In Reference to 510(k) number K140537/S001, please find the revised eCopy with the corrected PDF naming convention.

The eCopy is an exact duplicate of the paper copy except for the revised cover letter.

If you have any questions and/or concerns, please call or e-mail me using the information below.

Sincerely,

Helen Ragus

Helen Ragus
Regulatory Specialist
(805) 346-3700, X2932
hragus@denmat.com